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April 27, 2020

VIA ECF

The Honorable Robert B. Kugler
United States District Judge
District of New Jersey

The Honorable Joel Schneider
United States Magistrate Judge
District of New Jersey

Re: In re Valsartan, Losartan, and Irbesartan Products Liability Litigation
Case No. 1:19-md-02875-RBK-JS

Dear Judge Kugler and Judge Schneider:

This letter is to provide Defendants' positions with respect to the topics on the agenda for the Case Management Conference on April 29.

1. MDL Management

At the Court's direction, on March 9, 2020 the parties filed letter briefs setting forth their views as to how this MDL should be "managed and tried, including Fed. R. Civ. P. 12(b), class certification and *Daubert* issues." ECF 388. Based on decades of precedent, Defendants proposed a schedule that would commence with an omnibus Rule 12(b) motion to address the claims raised in the Economic Loss Master Complaint ("Master Complaint"), followed by an omnibus class certification motion, *Daubert* proceedings on scientific issues, Rule 56 motions, and a trial involving the claims, classes, and Defendants as narrowed by these prior rulings.[1] *See* ECF 393.

[1] Defendants note that their proposal is based on the Court's desire to proceed with an economic loss case as the first trial in this MDL. Defendants maintain that the most effective and efficient means of narrowing this litigation would be to allow motions to dismiss and *Daubert* briefing on

Defendants' proposal would evince the purpose of an MDL: to enhance efficiencies by streamlining the proceedings. *See* ECF 393 at 1–2 (attached as Exhibit A); *see also, e.g., Gelboim v. Bank of Am. Corp.*, 135 S. Ct. 897, 903 (2015). In contrast, Plaintiffs proposed a series of at least four separate, staggered class certification motions—and then trials—based on groupings of API manufacturers and the range of Defendants that supply valsartan containing their API. *See* ECF 392. Under Plaintiffs' plan, a "ZHP Track" would run the class certification and trial gauntlet first, followed by the "Mylan Track," the "Hetero Track," and, finally, the "Aurobindo Track." *See id.* Plaintiffs' proposal is novel and would sabotage this MDL with duplication, delay, and uncertainty.

After the parties submitted their positions on MDL management, the Sixth Circuit Court of Appeals granted a Petition for a Writ of Mandamus filed by a group of pharmacy defendants in the MDL styled *In re: National Prescription Opiate Litigation,* which bears directly on the MDL management issues in question. In particular, there, in response to the pharmacies' claim that the MDL court had deprived them of the opportunity to file a motion to dismiss under Rule 12(b), and thus forced them to incur the cost of burdensome discovery in response to defective claims, the Sixth Circuit stressed that Rule 12(b) is not an optional procedure and is key to enhancing the efficiency of an MDL. *See* No. 20-3075, *On a Petition for Writ of Mandamus*, No. 1:17-md-02804, at 9 (6th Cir. 2020) (attached as Exhibit B) ("Rule 12(b) states that 'a party *may* assert' the defenses enumerated therein 'by motion,' which means that the district court may *not* refuse to adjudicate motions properly filed under that Rule."). Defendants' proposal for an omnibus Rule 12(b) motion under the Master Complaint over the coming months is consistent with the Sixth Circuit's Writ of Mandamus. In contrast, Plaintiffs' proposal for separate, staggered dispositive motions to be filed by the defendants in each so-called "API Track" that would follow the class certification of each such track must be rejected as seriously prejudicing Defendants' right to seek dismissal of improper claims early in the litigation. *See* Ex. B at 9 ("[The] Rules are binding upon the court and parties alike, with fully the force of law." (citing *Bank of Nova Scotia v. United States*, 487 U.S. 250, 255 (1988) and other decisions)).

Recent changes to the MDL's schedule also weigh in favor of proceeding with the omnibus Rule 12 motion Defendants have proposed. Due to the disruptions that COVID-19 has caused to businesses globally, the Court recently ordered an extension of the Manufacturer Defendants' discovery deadlines. *See* ECF 416. The Manufacturers now have until November 29, 2020 to complete their document productions, with rolling productions of documents being made on May 15, July 15, and the first day of September-November—although the scope of the downstream defendants' discovery obligations will not be determined until the Court rules on certain macro issues and the parties finalize the applicable discovery requests based on such rulings. Thus, the

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the personal injury cases, where the issue of general causation could prove wholly dispositive. The Court has previously noted that while the economic loss case is the focus of the next phase of this MDL, the personal injury cases can and should continue to proceed on a parallel litigation track, and therefore Defendants intend to proceed with affirmative discovery and depositions of the plaintiffs and witnesses in the personal injury cases.

coming months present an opportune time for the Court to address dispositive and claim-narrowing issues through Rule 12 briefing. Indeed, further delaying Rule 12 motions in this case—potentially beyond the production of costly, voluminous discovery—would contradict the long-standing precedent cited in Defendants' opening letter brief, and reaffirmed by the Sixth Circuit, that Rule 12 motions should be decided early in the litigation. *See Manual for Complex Litigation* § 21.133 at 253.[2]

Plaintiffs' so-called "API Tracks" are also at odds, *and fundamentally so*, with the principle, reiterated by the Sixth Circuit, that "an MDL court must find efficiencies within the Civil Rules, rather than in violation of them." Ex. B at 6. Approximately 33 class action complaints have been transferred to or directly filed in the MDL, and not one asserts class action claims based on a theory of "API Tracks." Moreover, of the 24 class representatives named in the Master Complaint, only 16 filed individual class action complaints distinct from the Master Complaint in transferor jurisdictions. If Plaintiffs are correct, and the Master Complaint is merely an "administrative summary" of the previously filed class actions, then upon class certification in the MDL, to which jurisdiction will this Court remand the case for trial, and which "API Track" will be so remanded? In actuality, the only logical conclusion to be drawn from the difference between the class representatives named in the Master Complaint and the class representatives who filed individual actions in other jurisdictions is that the Master Complaint supersedes all of the other class action complaints and is the only legally operative class action complaint. *See Gelboim*, 574 U.S. at 413 n.3 (citing *In re Refrigerant Compressors Antitrust Litig.*, 731 F.3d 586, 590–92 (6th Cir. 2013)); *see also In re General Motors LLC Ignition Switch Litig.*, No. 14-md-2543, 2015 WL 3619584, at *7–8 (S.D.N.Y. June 10, 2015). Given that a trial in this Court can be had only on the claims and parties over which this Court has jurisdiction, it is obvious that Plaintiffs still have a lot of groundwork to do to identify class representatives who have standing to sue each of the Defendants in each of the so-called API Tracks. For example, there is only one class representative who is from New Jersey,[3] and she claims to have received valsartan from only one manufacturer

[2] For example, all claims based on Defendants' alleged representations are preempted. *See* Defendants' letter seeking leave to file Rule 12 motions, ECF 174 at 3. In addition, many Retailers/Pharmacies, Distributors, and Wholesalers are entitled to dismissal for lack of standing or under innocent seller statutes. *See id.* at 5. Once Rule 12 motions are decided and claims are eliminated or narrowed, the scope of discovery must be narrowed to be relevant and proportional to the surviving claims, if any.

[3] The 23 other class representatives named in the Master Complaint are from Alabama (1), California (1), Connecticut (1), Florida (1), Georgia (1), Indiana (2), Kansas (1), Louisiana (1), Massachusetts (1), New Mexico (1), New York (4), North Carolina (1), Ohio (1), Pennsylvania (1), South Carolina (1), Texas (2), and Virginia (2). It simply stretches the imagination to believe that each of these class representatives has standing to bring claims under their state's laws against each of the dozens of Defendants that would comprise each of the so-called "API Tracks." The Court cannot certify a state-specific sub-class as to a Defendant without such standing being established as to that Defendant. *See 6803 Blvd. East, LLC v. DIRECTV, LLC*, 17 F. Supp. 3d 427,

and one pharmacy. Thus, by definition, a New Jersey sub-class would be limited to only a handful of defendants, assuming this class representative can even trace the valsartan she purchased to each such Defendant.

Acknowledging that the Master Complaint does not identify class representatives who are able to assert claims against all Defendants in each proposed "API Track," Plaintiffs' letter brief asserts that "Class Certification will be sought ***by the appropriate representative plaintiffs***," apparently to be named later, followed by a trial against all Defendants in a particular API Track. ECF 392 at 3 (emphasis added). But determining "appropriate" representative plaintiffs is a critical element of the plaintiffs' initial pleading and later class certification burden. The time to identify appropriate representative plaintiffs is now. In any event, Plaintiffs' plan of action would logistically require discovery to restart as to every class representative that might eventually be named. Thus, in addition to ignoring basic rules of civil procedure, Plaintiffs' proposal for a series of class certification motions grouped around particular Defendants would create significant delay, particularly if Plaintiffs are permitted to continually search for and identify new class representatives to support their novel structure. In short, to avoid a seemingly never-ending piecemeal approach and to ensure the just and efficient resolution of these actions (as required by Fed. R. Civ. P. 1), should any claims survive an omnibus Rule 12(b) motion, the Court should proceed with an omnibus class certification motion in which all representatives named in the Master Complaint seek certification as to all defendants against whom the representatives have standing to sue.

Plaintiffs' proposal for separate API Tracks is simply unsupported by controlling legal precedent. While MDL courts may use "tracks" to organize the proceedings, such tracks must be consistent with the Rules of Civil Procedure and not abridge the rights of the parties. Unless each API Track completes class certification proceedings, including hearings and notice and opt-out periods, before a merits-decision as to any of the API Tracks, Plaintiffs' plan would violate the single intervention rule. Even if Plaintiffs could identify enough class representatives who could establish standing against all of the Defendants in each such API Track, or even more than just a small handful of Defendants, it could take years to complete each of the separate class certification proceedings. The delay, complexity, uncertainty, and burden Plaintiffs' novel proposal would impose on the parties and the Court is unwarranted. In addition to the reasons set forth in Defendants' prior briefing, and as further supported by the Sixth Circuit's Writ of Mandamus, the Court should adopt Defendants' proposal on how this MDL should be managed because it is consistent with the principles that Rule 12 motions should be decided early in the litigation and that tools used to manage MDL proceedings must stay within the bounds of the Rules of Civil Procedure in managing MDL proceedings. *See* Ex. B at 8.

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432 (D.N.J. 2014) (dismissing defendant from class action when "no named plaintiff" representing the class could "demonstrate any injury at the hands of th[at] particular defendant"); *Toll Bros., Inc. v. Twp. of Readington*, 555 F.3d 131, 138 n.5 (3d Cir. 2009).

2. Ongoing Negotiations Regarding Preliminary ESI Search Terms

Negotiations with respect to ESI search terms, ESI custodians, and Rule 34 document requests for the Manufacturer Defendants were conducted simultaneously during the fourth quarter of 2019. The process culminated with the entry of an Order on December 23, 2019, attaching the initial designated ESI search terms. (*See* Dkt. 328, Or.) The Court, however, has made clear that all discovery orders, including the search terms, are subject to modification on a showing of good cause. (*See, e.g.*, 12/11/19 CMC Tr. 26:17–23.)

Because the preliminary lists of document custodians were not finalized until late December, the Manufacturer Defendants did not begin the process of collecting and reviewing the records of those document custodians until January 2020. Having done so, it quickly became apparent that the breadth of the search terms, coupled with the large number of custodians, were generating an enormous number of hits on the Manufacturer Defendants' email custodial files.

To use Mylan as an example, running the initial search terms against the Outlook files of the 52 designated custodians has captured approximately five million emails out of a total population of 17 million, meaning that the ESI search terms are hitting on nearly one-third of all emails sent or received by those individuals over the span of nearly a decade. Obviously, given that Mylan manufactures hundreds upon hundreds of products worldwide, it would be nonsensical to suggest one out of every three emails exchanged by Mylan's custodians would have any relevance to whether one particular medication, valsartan, contained an impurity.

What's more, the combined volume of emails and attachments within Mylan's custodial files that hit on the current search terms is more than 3.5 terabytes. Conservatively, it is estimated that an additional 500 gigabytes of non-custodial data will need to be collected, reviewed, and produced in response to Plaintiffs' Rule 34 requests. Combined, unless there is some modification to the search terms, Mylan estimates that its custodial and non-custodial document collections will span approximately 4 terabytes. For some perspective, this would be enough to fill the memory capacity of approximately 6,000 CD-ROMs.

Mylan's experience with the search terms is not unique. The initial search terms are capturing over 44% of all documents contained in the email files of the Teva Defendants' custodians. The Teva Defendants conservatively estimate these custodial email files alone will contain over 4 terabytes of information and 4–5 million unique documents requiring review under the current search terms protocol. As would be expected, on preliminary review, a large number of these documents are proving to be wholly irrelevant to this litigation.

The bottom line is that, as presently constructed, the preliminary search terms are capturing a staggering amount of overly broad data which will cost millions of dollars to process, review, and produce. Back in January, therefore, the Manufacturer Defendants reached out to Plaintiffs' Executive Committee to begin the meet-and-confer process to tailor the ESI search terms to more precisely track potentially relevant and responsive materials. Initially, those efforts focused on particularly problematic terms that were generating a disproportionate number of false positives.

However, incremental adjustments did not result in any meaningful reduction of the overall dataset due to extensive overlap among the more than 400 designated search terms.

Accordingly, on March 19, Mylan submitted a counterproposal to Plaintiffs which—while maintaining the general framework contemplated by the parties in December—included necessary modifications to the search protocol to reduce overbreadth through the use of modifiers and the elimination of certain terms. At Plaintiffs' request, Mylan has also provided detailed spreadsheets demonstrating the significant gains to be realized using the streamlined counterproposal, including dramatically lower hit counts (1.2 million versus five million) and a 50% reduction in the volume of captured data.

For purposes of uniformity and to simplify the meet-and-confer process, the other Manufacturer Defendants have since agreed to adopt Mylan's revised search terms as a global counterproposal. The Manufacturer Defendants look forward to continuing to work with Plaintiffs to narrow the ESI search terms to more reasonably reflect the needs of this case. Per Judge Schneider's instructions during the April 15 telephonic status conference, should the parties fail to reach an agreement, the Manufacturer Defendants will make an application to the Court for appropriate relief. (See Dkt. 416, Or.)

Respectfully submitted,

/s/ Seth A. Goldberg

Seth A. Goldberg

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